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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,316	12/01/2005	Roger Victor Bonnert	06275-450US1	4511

26164 7590 03/11/2008

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EXAMINER	
MOORE, SUSANNA	
ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,316	BONNERT, ROGER VICTOR	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's argument, see Remarks, filed 12/27/2007, with respect to the rejection(s) of claim(s) 1 and 9 have been fully considered. Since no new rejections are being made, this is a Final Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

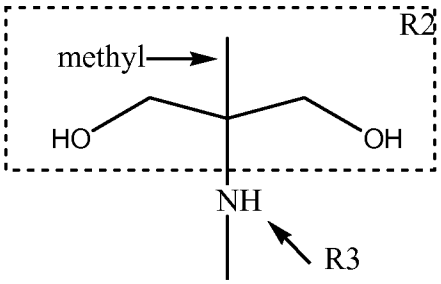
evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Willis et. al. (WO 01/25242, US equivalent is 6790850) in view of Berge et. al. (J. of Pharm. Sciences, 1977, pages 1-19).

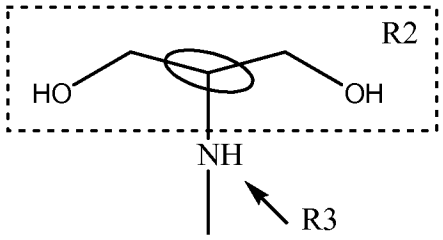
The instant Application teaches a compound of formula (I) and the process of making said compound, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)propyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one.

Willis et. al. claims the following specie, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, and a method of synthesizing said specie. See claim 4 for the specie and the process in claim 7.

The difference between the instant invention and the reference is at the 7-amino substituent. Although the conflicting claims are not identical, they are obvious variants because the specie found in claim 4 of the referenced patent, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

This is just one specie of the many that render the compounds obvious over the instant Application.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant traverse the above rejection by stating the instant Application is directed to a particular salt of the compound indicated in claim 1. The reference cited covers pharmaceutically acceptable salts of the compounds, see claim 1, column 38, lies 28-29 and column 9, line 3, which indicates sodium as an acceptable salt. It would be obvious of one of ordinary skill in the art to make the sodium salt of the above-mentioned compound because sodium is one of the specific salts taught in the reference. Furthermore, Berge teaches sodium as one of the most frequent cationic salts used/made prior to 1977, see Table 1 and the left-hand column, lines 12-13.

Applicant has provided an affidavit with unexpected results achieved with the sodium salt of the compound of claim 1. However, based on the Berge reference cited above, it would be obvious to one of ordinary skill in the art to choose sodium as a salt to achieve better results than

the free compound or other salts. Thus, the affidavit is not sufficient to overcome the art rejection and the rejection is maintained.

The provisional rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being obvious over copending Application No. 10863995 which has a common assignee with the instant application is withdrawn. This case is a related case with the same disclosure as the '850 patent cited above. Thus, the response is the same as that indicated above.

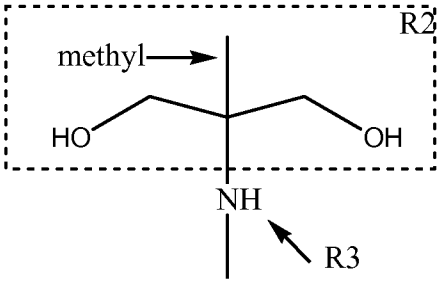
Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

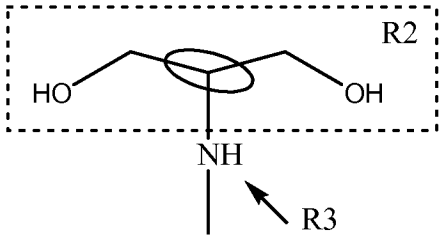
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,790,850. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 4, lines 54-56, of the referenced patent, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

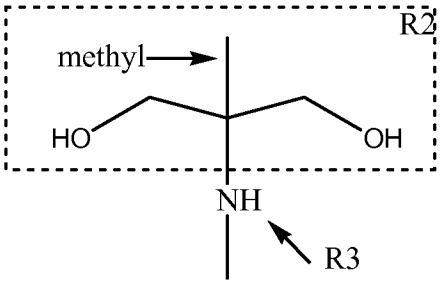
Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states, "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

The compositions, method of making and method of treatment claims all overlap in scope.

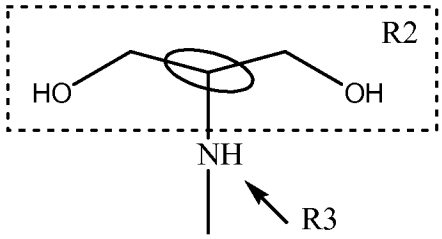
Applicant traverse the above rejection by using the same argument as stated above for the 103 art rejection. Thus, the same response given for the traversal above applies here too.

Claims 1 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-26 of copending Application No.

10863995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 4, lines 54-56, of the referenced patent, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

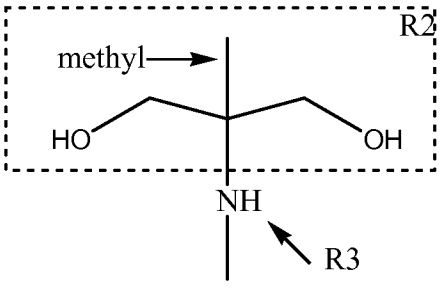
The same homolog/positional isomer argument used above applies here. The compositions, method of making and method of treatment claims all overlap in scope.

The instant Application is drawn to a method of treating arthritis with said compounds. The copending Application discloses the compounds as antiarthritic agent. See page 13. This is just one of the many obvious species that renders said claims obvious over the copending Application.

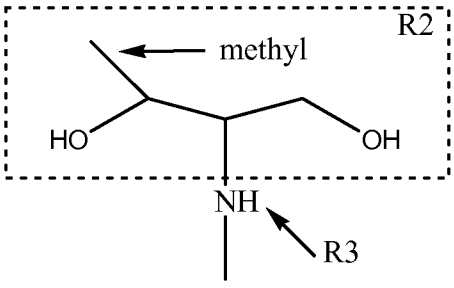
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant traverse the above rejection by using the same argument as stated above for the 103 art rejection. Thus, the same response given for the traversal above applies here too.

Claims 1 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of copending Application No. 10528270. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 1 of formula (I) of the co-pending application, 5-[[(2,3-difluorophenyl)methyl]thio]-7-[2-hydroxy-(1-hydroxymethyl))propyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one, is a positional isomer of the specie found in claim 1 of the instant application. The difference between the two compounds is the location of the methyl group illustrated below.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

The same homolog/positional isomer argument used above applies here. The compositions, method of making and method of treatment claims all overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant traverses the above rejection by stating the instant invention is claiming a particular salt, there are two chemical centers in the compound of the copending Applicantion, which produces a particular stereoisomer, and as such, these compounds are not obvious variants.

This is not found persuasive. Claim 1 of the copending Application claims pharmceutically acceptable salts, see claim 1. Furthermore, Berge et. al. teaches sodium as a pharmaceutically acceptable salt. Moreover, a particular stereoisomer is close enough structurally to render a different stereoisomer obvious. The M.P.E.P. states (2144.08) In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Thus, the rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624